

STATE OF MICHIGAN
DEPARTMENT OF INSURANCE AND FINANCIAL SERVICES
Before the Director of Insurance and Financial Services

In the matter of:

██████████
Petitioner

v

Blue Care Network of Michigan
Respondent

File No. 154052-001

Issued and entered
this 19th day of July 2016
by Randall S. Gregg
Special Deputy Director

ORDER

I. BACKGROUND

On June 15, 2016, ██████████, authorized representative of ██████████ (Petitioner), filed a request with the Director of Insurance and Financial Services for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Petitioner receives prescription drug coverage through an individual plan underwritten by Blue Care Network of Michigan (BCN), a health maintenance organization. The Director notified BCN of the external review request and asked for the information used to make its final adverse determination. BCN provided its response on June 17, 2016. On June 22, 2016, after a preliminary review of the material submitted, the Director accepted the request.

Because the case involves medical issues, it was assigned to an independent medical review organization which provided its analysis and recommendation to the Director on July 6, 2016.

II. FACTUAL BACKGROUND

The Petitioner is 59 years old and has plaque psoriasis. To treat that condition her dermatologist prescribed Otezla. BCN denied coverage for the drug.

The Petitioner appealed the denial through BCN's internal grievance process. At the conclusion of that process, BCN issued a final adverse determination dated May 19,

2016, affirming its denial of coverage. The Petitioner now seeks the Director's review of the denial.

III. ISSUE

Did BCN properly deny prescription drug coverage for Otezla?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination BCN stated that it had denied coverage because the Petitioner had not met its requirement that an individual first use Enbrel and Humira. According to BCN, it will provide coverage for Otezla only if Enbrel or Humira treatment is unsuccessful.

Petitioner's Argument

In a letter of May 31, 2016, submitted with the Petitioner's request for an external review, the Petitioner's dermatologist wrote:

[Petitioner] ... suffers from plaque psoriasis....Her symptoms include red, itchy, scaling rough plaques on bilateral elbows and hands, right knee, ears, face, and left foot, affecting over 20% of [her body surface area]. She has tried and failed Kenalog spray, Ultravate ointment, Vectical, Clobetasol ointment, Methotrexate, and Epiduo. [Petitioner's] psoriasis flare ups, causes joint pain and hinders her ability to work as a hair dresser. The denial states that [Petitioner] must have a previous treatment with or contraindication, or intolerance to Humira or Enbrel. In September, 2008 The Food and Drug Administration ordered stronger warnings on four anti-TNF-a drugs Enbrel, Remicade, Humira and Cimzia stating they can raise the risk of possibly fatal fungal infections in addition to both Humira and Enbrel suppress the immune system. In September 2014, Otezla was approved for moderate to severe plaque psoriasis and psoriatic arthritis by regulating inflammation within immune cells. By helping to control inflammation, Otezla improves joint tenderness and swelling in people with psoriatic arthritis, and redness and scaliness of plaque psoriasis. In clinical trials, about 31 percent of the individuals taking Otezla experienced a 75 percent improvement in the severity of their psoriasis after four months. Furthermore, Otezla is an oral medication eliminating painful injections, bruising and possible swelling of the injection sites, and Otezla is less expensive than biologic treatments such as

Enbrel or Humira. I strongly feel that Otezla therapy is [Petitioner's] best treatment option at this time. Without this treatment I fear her condition will continue to worsen causing increased pain and suffering as well as limiting her ability to use her hands to continue as a hairdresser.

Director's Review

BCN provides coverage for Otezla subject to prior approval and quantity limits. One requirement for receiving prior approval is that an individual must first have tried Enbrel or Humira without success. The Petitioner has not been treated with either drug.

BCN's requirements for approval of Otezla were presented to an independent review organization (IRO) for analysis as required by section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician who is board certified in dermatology and has been in practice for more than 10 years. The IRO reviewer's report included the following analysis and conclusion:

The member has tried and failed treatment with topical steroids (clobetasol ointment), triamcinolone spray, Vectical ointment and methotrexate. The Health Plan denied the member's request for coverage of Otezla as she has not met its step therapy criteria because she has not tried and failed therapy with the preferred biologic agents Enbrel and Humira ... [T]here is no documentation that the member has a contraindication or intolerance to either of these preferred biologic agents ... [W]hile treatment of plaque psoriasis is considered medically necessary, the use of Otezla specifically is not indicated as the member has not tried and failed conventional biologic therapies, which often have a greater efficacy of treatment of plaque psoriasis ... [C]urrently, the Health Plan's guidelines for coverage of Otezla are consistent with policies of other major insurers.

Pursuant to the information set forth above and available documentation ... Otezla is not medically necessary for treatment of the member's condition. (Gisondi P, et al. Apremilast in the therapy of moderate-to-severe chronic plaque psoriasis. *Drug Des Devel Ther.* 2016 May;1:01763-70. Ritchlin CT, et al. New therapies for psoriasis and psoriatic arthritis. *Curr Opin Rheumatol.* 2016 May;28(3):204-10.)

The Director is not required to accept the IRO's recommendation. *Ross v Blue Care Network of Michigan*, 480 Mich 153 (2008). However, the IRO's recommendation is afforded deference by the Director. In a decision to uphold or reverse an adverse

determination, the Director must cite “the principal reason or reasons why the [Director] did not follow the assigned independent review organization’s recommendation.” MCL 550.1911(16)(b).

The IRO’s analysis is based on extensive experience, expertise and professional judgment. In addition, the IRO’s recommendation is not contrary to any provision of the Petitioner’s coverage. MCL 550.1911(15). The Director can discern no reason why the IRO’s recommendation should be rejected in the present case. The Director, therefore, finds that BCN may require treatment with Enbrel or Humira as a precondition to approval of coverage for Otezla.

V. ORDER

The Director upholds BCN’s May 19, 2016 final adverse determination. BCN is not required, at this time, to provide coverage for the prescription drug Otezla.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this order may seek judicial review no later than sixty days from the date of this order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Department of Insurance and Financial Services, Office of General Counsel, Post Office Box 30220, Lansing, MI 48909-7720.

Patrick M. McPharlin
Director

For the Director

A handwritten signature in black ink, appearing to read 'RSG', is written over a horizontal line.

Randall S. Gregg
Special Deputy Director